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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,811	04/05/2006	Gilles Pauly	C 2708 PCT/US	9595
23657 7590 03/22/2007 COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			EXAMINER NGUYEN, HUONG Q	
			ART UNIT	PAPER NUMBER
			3736	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/530,811

Applicant(s)

PAULY ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the preliminary amendment filed 4/8/2005.
Amendments to the specification and the abstract are acknowledged. Claims 1-18 are cancelled.
Claims 19-38 are new and pending.

Priority

2. The instant application is acknowledged as a 371 of PCT/EP03/10766 filed 9/27/2003, which claims priority from French application 0212462 filed 10/8/2002.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 4/8/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the processing element, the recording element, and the microprocessor of the evaluation circuit of **Claims 19 and 27** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

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even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 19-21, 26-27, 31-32, and 38** are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (US Pat No. 5540235).

7. In regards to **Claim 19**, Wilson discloses a method for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said method comprising:

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(a) providing a skin substrate to be analyzed; (b) applying a first non-invasive electrode (11) to a measuring point of the skin substrate; (c) applying a second non-invasive electrode (11) to a second point of the skin substrate, best seen in Figure 1; (d) subjecting the skin substrate to stimulation (7); and (e) analyzing a change in an electrical signal detected by the first and second non-invasive electrodes (Col. 28-36); wherein the first and second non-invasive electrodes are associated with an evaluation circuit (abst) for analyzing the electrical signal detected by the first and second non-invasive electrodes, the evaluation circuit comprising at least one amplifying element (51), at least one processing element (53), at least one recording element (Figure 6), and at least one microprocessor or computer (1), best seen in Figure 6.

8. In regards to **Claim 20**, Wilson discloses the stimulation (7) (Col.6: 42-43) comprises electrical stimulation (Col.2: 28-35).

9. In regards to **Claim 21**, Wilson discloses the electrical stimulation (7) is provided by a stimulation circuit comprising at least two stimulation electrodes (38) in contact with an area of the skin substrate subject to the stimulation and an electrical stimulator (33) connected to the microprocessor (1), best seen in Figures 1 and 3 (Col.6: 42-49).

10. In regards to **Claim 26**, Wilson discloses applying a weak alternating current (Col.5: 50) to the first non-invasive electrode and measuring the impedance of the skin substrate.

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11. In regards to **Claim 27**, Wilson discloses an apparatus for non-invasive, in vivo determination of the conductivity of nerves in a region of skin, said apparatus comprising: (a) at least one non-invasive measuring electrode (11) suitable for detecting a signal representative of the electrical activity of (i) a sensory nerve of a skin substrate or of (ii) the brain (Col.2: 28-37); (b) an electronic stimulator (7) connected to at least one stimulation electrode (38); (c) at least one reference electrode (11), best seen in Figure 1 (Col.2: 30); (d) a circuit connected to the at least one non-invasive measuring electrode, the electronic stimulator, and the at least one reference electrode for evaluating signals detected or transmitted by said electrodes, the circuit comprising at least one amplifying element (51), at least one processing element (53), at least one recording element (Figure 6), and at least one microprocessor or computer (1); such that a curve representative of change in the signal detected by the at least one non-invasive measuring electrode after a stimulation, as a function of time, can be created and displayed (abst).

12. In regards to **Claim 31**, Wilson discloses at least two non-invasive measuring electrodes, best seen in Figure 1, wherein at least one non-invasive measuring electrode is capable of measuring impedance of the skin substrate.

13. In regards to **Claim 32**, Wilson discloses at least one adjustable voltage generator (35) associated with at least one transmitting aerial (15) erected in proximity to the at least one non-invasive measuring electrode (11) capable of measuring impedance, best seen in Figure 1A and 3A.

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14. In regards to **Claim 38**, Wilson discloses the at least one processing element comprises an analog/digital converter (52).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Denda et al (US Pub No. 20040106877).

17. Wilson discloses method of stimulating the skin substrate but does not disclose said skin substrate further subjected to a stress. Denda et al teach subjecting a skin substrate to stress and comparing a measured electrical signal with stress between a measured electrical signal without stress to effectively determine the effects of the stress (§10010). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wilson such that the stimulated skin substrate is further subjected to a stress and an electrical signal detected by the first and second non-invasive electrodes with the stress is compared to the electrical signal detected by the first and second non-invasive electrodes without the stress, as taught by Denda, as an effective method of determining the effects of the stress on the skin substrate.

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18. **Claims 23-25 and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Northrop (US Pub No. 20030045922).

19. In regard to **Claims 23-25**, Wilson discloses the method above but do not disclose said first non-invasive electrode positioned on facial skin to transmit signals representative of electrical activity of at least one branch of a facial trigeminal nerve. Northrop teaches placing electrodes on facial skin such that electrical activity of at least of one branch of a facial trigeminal nerve selected from the group consisting of an ophthalmic branch, a maxillary branch, a mandibular branch and combination thereof (§0044-0045) can be obtained to gather valuable information pertaining to facial nerves and for the subsequent treatment thereof, best seen in Figure 1-3. Furthermore, although Northrop does not explicitly disclose electrical contact with the maxillary branch, it is obvious to one of ordinary skill in the art that the placement of said electrodes, best seen in Figure 3, would enable electrical contact with said maxillary branch due to its known location on the face coinciding with that of said electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the first non-invasive electrode on facial skin such that it is capable of transmitting signals representative of the electrical activity of at least of one branch of a facial trigeminal nerve selected from the group consisting of an ophthalmic branch, a maxillary branch, a mandibular branch and combination thereof, and in particular the maxillary branch, as taught by Northrop, to gather valuable information pertaining to facial nerves and allow the subsequent treatment thereof.

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20. In regards to **Claim 30**, Wilson discloses the apparatus above but does not disclose at least one non-invasive measuring electrode connected to an adjustable connected to an adaptable holder. Northrop teach an adaptable holder (16) and an adjustable arm (31) having a first (21) and second (22) end, wherein the first end is connected to the adaptable holder, and wherein at least one electrode (40A-D) is connected to the second end, best seen in Figures 2-3, as an effective means to secure the electrodes to the head to allow electrical contact with the facial skin and nerves (Col. ¶0035). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place at least one non-invasive measuring electrode of Wilson on an adjustable arm connected to an adaptable holder described above, as taught by Northrop, as an effective means to secure the at least one non-invasive measuring electrode to the head for the desired facial nerve analysis.

21. **Claims 28-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Dunseath, Jr (US Pat No. 5003978).

22. Wilson discloses at least one non-invasive measuring electrode above but does not disclose said electrode as non-polarizable or comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof. Dunseath, Jr teach the use of a non-polarizable electrode for advantages such as the ability to withstand high voltage overloads (Col.1: 36-44) comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof (Col.5: 1-5) as effective materials for said non-polarizable electrode. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least one non-invasive measuring electrode of

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Wilson non-polarizable and comprising a material selected from the group consisting of stainless steel, tungsten, noble metals and mixtures thereof, as taught by Dunseath, Jr, as an effective means to obtain the benefits associated with use of a non-polarizable electrode such as high voltage capacity.

23. **Claims 33-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Miyata et al (US Pat No. 6026321).

24. In regards to **Claim 33**, Wilson discloses at least one amplifying element comprising at least one preamplifier (51). However, Wilson does not disclose the at least one preamplifier having a high input impedance over a voltage range of from -3 to +3 volts. Miyata et al disclose an amplifier having a high input impedance over a voltage range of from -3 to +3 volts (Col.6) as an effective value for skin measuring electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to having the at least one preamplifier of Wilson have a high input impedance over a voltage range of from -3 to +3 volts as taught by Wilson as an effective value for the skin measuring application.

25. In regards to **Claim 34**, Wilson discloses the at least one preamplifier (51) is connected directly to the at least one reference electrode through Pins 45 and 46 (Col.8: 23-31), best seen in Figure 4d.

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26. In regards to **Claim 35**, Wilson discloses the at least one preamplifier (51) is connected directly to the non-invasive measuring electrode through Pins 45 and 46 (Col.8: 23-31), best seen in Figure 4D.

27. **Claims 36-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Miyata et al, further in view of Bergman et al (US Pat No. 4257010).

28. In regards to **Claim 36**, Wilson as modified by Miyata et al above discloses at least one preamplifier connected to the non-invasive measuring electrode but do not disclose the at least one preamplifier is connected to the non-invasive measuring electrode by a shielded cable. Bergman et al disclose connecting wires (13a,b) surrounded by shielding (16) to prevent interference between the wires (Col.5: 44-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect the at least one preamplifier to the non-invasive measuring electrode by a shielded cable to prevent unwanted interference between proximal connecting wires.

29. In regards to **Claim 37**, Wilson as modified by Miyata et al and Bergman et al above disclose the shielded cable comprises a shield connected to an output of the at least one amplifying element (Col.5: 50-58).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



HQN
3/19/2007

